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# PRINTER RUSH

(PTO ASSISTANCE)

Application : 09/284436 Examiner : George GAU : 16/6  
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DOC CODE	DOC DATE	MISCELLANEOUS
<input type="checkbox"/> 1449		<input type="checkbox"/> Continuing Data
<input type="checkbox"/> IDS		<input type="checkbox"/> Foreign Priority
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<input type="checkbox"/> IIFW		<input type="checkbox"/> Fees
<input type="checkbox"/> SRFW		<input type="checkbox"/> Other
<input type="checkbox"/> DRW		
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<input checked="" type="checkbox"/> SPEC	<u>4/12/99</u>	

[RUSH] MESSAGE: Please add a paragraph in the Specification citing  
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BIOCERAMIC COMPOSITIONS

## Background of the Invention

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Much research in the area of biopharmaceutics is directed toward the development of effective implantable vehicles for drug delivery and other surgical applications. Such vehicles must be biocompatible and also must be capable of protecting the activity of any biologically active agent they are intended to deliver. Many biologically active agents are labile and easily lose activity when they are incorporated into a delivery material.

10 Preservation of protein activity has posed particularly difficult problems.

In the drug delivery arena, calcium phosphate ceramics have been studied as potential delivery vehicles due to their well known biocompatibility and their affinity for protein reagents (see, for example, Ustema et al., *Int. J. Pharm.* 112:215, 1994; Itokazu et al., *J. Orth. Surg.* 2:47, 1994; Shinto et al., *J. Bone Joint Surg.* 74-B:600, 1992; Uchida et al., *J. Orth. Res.* 10:440, 1992). However, the reactions employed to produce known calcium phosphate ceramic materials typically require elevated temperatures and/or pressures, and also require the presence of acids or bases. Because most biologically active agents would be destroyed by one or more of the conditions required to produce the ceramic, the biologically active agents can only be loaded in after the material is produced, which can limit the amount and type of agent that can be delivered.

20 Also, although a number of calcium phosphate materials have been referred to as "resorbable", such compounds, usually comprising or derived from tricalcium phosphate, tetracalcium phosphate or hydroxyapatite are in fact only weakly resorbable. Of the group, the tricalcium phosphate compounds have been demonstrated to be the most resorbable and, after many years of study, they are still not widely used in clinical

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09/284,436

This application is a 371 of PCT/US97/18528 filed October 16, 1997, which is a continuation-in-part of serial number 08/729,354 filed October 16, 1996 now patent number 6,132,463, and is a continuation-in-part of serial number 08/729,342 filed October 16, 1996.



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Bib Data Sheet

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<b>APPLICANTS</b> Dosuk D. Lee, Brookline, MA; Christian Rey, Castanet, FRANCE; Maria Aiolo, Brookline, MA; Aliassghar Tofighi, Belmont, MA;				
<b>** CONTINUING DATA *****</b> This application is a 371 of PCT/US97/18528 10/16/1997 <i>Kathy r Shulborne</i> which is a CIP of 08/729,354 10/16/1996 PAT 6,132,463 <i>1016</i> and is a CIP of 08/729,342 10/16/1996 <i>424/484</i>				
<b>** FOREIGN APPLICATIONS *****</b> <div style="text-align: right;">** SMALL ENTITY **</div>				
Foreign Priority claimed <input type="checkbox"/> yes <input checked="" type="checkbox"/> no 35 USC 119 (a-d) conditions <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Met after Verified and <i>Allowance</i> Acknowledged <i>ve</i> Examiner's Signature _____ Initials _____		<b>STATE OR COUNTRY</b> MA	<b>SHEETS DRAWING</b> 22	<b>TOTAL CLAIMS</b> 22
				<b>INDEPENDENT CLAIMS</b> 3
<b>ADDRESS</b> Mary Rose Scozzafava Clark & Elbing 176 Federal Street Boston, MA 02110				
<b>TITLE</b> Bioceramic compositions				
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